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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,178	07/18/2003	Yoshihiro Mori	09496/000M861-US0	2675
7278	7590	03/21/2006	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/623,178

Applicant(s)

MORI ET AL.

Examiner

Leslie R. Deak

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/18/03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 9, 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 9, it is unclear what applicant means by "fixing means" between the drip chamber and the housing. In claim 15, it is unclear what applicant means by "compensating" the hematocrit values. Furthermore, the light emission means may not be turned off and flashing at the same time. As a result, the scope of the claims is unclear.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6 and 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,385,539 to Maynard.

In the specification and figures, Maynard discloses the apparatus and method as claimed by applicant. In particular, Maynard discloses a hematocrit sensor within a blood circuit that comprises a plasma separation system that may be used to "purify" the

blood for reinfusion to the patient (see column 3, lines 10-39). The sensor is located in a housing 90 with a slot in bottom half 124 for optical connector and hollow member 100, 102. The slot further comprises a slit or window 106, and light emission means and detection means 54, 56, 58 that all face the hollow member from the same side of the housing (see FIGS 9, 10, column 12, lines 22-39, column 11, lines 20-40, column 7, lines 45-50, column 8, lines 41-59).

With regard to claims 2-4, the housing 90 comprises a lid 120 connected to the housing by hinge 126 and a locking arm 122 that holds the cover in place (see FIG 9).

With regard to claims 5 and 6, the hematocrit sensor may be connected to a microprocessor that may function to detect the presence of the sensor in the housing. Applicant further sets forth the mode of operation of the claimed blood treatment device. However, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114.

With regard to claims 14, 15, as best understood, and 16-18, Maynard discloses that the light emitter provides light in the direction of blood flowing through the tube 102, the detector detects the amount of light back-scattered against the blood sample, determining the amount of light reflected, and generating a signal reflective of the hematocrit in the blood sample based on the amount of reflected light (see column 9, lines 18-55). In an alternate embodiment, the sensor is connected to a microprocessor that calculates hematocrit values and regulates the operation of the extracorporeal

circuit based on the calculated hematocrit value (see column 13, lines 10-23). The hematocrit sensor disclosed by Maynard functions when the light source is pulsed (see column 9, lines 14-16), and may be used to signal the beginning or the end of a transfusion cycle (see column 13, lines 43-50). The sensor further comprises a method for calibrating the light coming from the emitter, when compared against a reference value, in order to compensate for changing conditions in the sample area, which may include blood flow rate (see column 9, lines 35-46).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,385,539 to Maynard, as applied above.

In the specification and figures, Maynard discloses the device substantially as claimed by applicant with the exception of an adjustable slit or pore size. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the openings adjustable, since it has been held that the provision of adjustability, where needed, involves only routine skill in the art. See MPEP § 2144.04.

7. Claims 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,385,539 to Maynard, as applied above, in view of US 6,582,385 to Burbank et al.

In the specification and figures, Maynard discloses the device substantially as claimed by applicant with the exception of a pump, substitution fluid, and a dialyzing fluid. Maynard specifically discloses, however, that his hematocrit sensor may be deployed in any extracorporeal blood circuit in order to control the progress of the blood through the circuit based on the measured hematocrit value (see column 4, lines 11-23).

Burbank discloses a dialysis system with pump 20 that passes blood to a hemofilter, ultrafiltrate pump 47, replacement fluid, dialysis fluid, a drip chamber, flow detector, and an air bubble detector (see columns 6-8). The drip chamber may be connected to a hematocrit sensor that may, in turn, control the operation of the extracorporeal circuit. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the extracorporeal system disclosed by Maynard with the extracorporeal dialysis circuit disclosed by Burbank to operate with the Maynard hematocrit sensor in order to allow the sensor to control the extracorporeal circuit, as taught by Maynard.

### ***Conclusion***

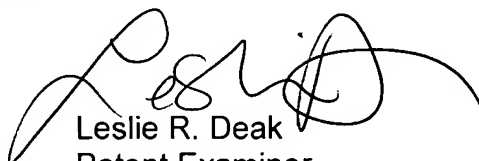
8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 4,745,279 Karkar et al
- i. Hematocrit measuring apparatus

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

~~If attempts to reach the examiner by telephone are unsuccessful, the examiner's~~  
supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leslie R. Deak  
Patent Examiner  
Art Unit 3761  
13 March 2006